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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/759,746

01/16/2004

Ester Fernandez-Salas

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ALLERGAN, INC.

2525 DUPONT DRIVE, T2-7H

IRVINE, CA 92612-1599

EXAMINER

WANG, CHANG YU

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

07/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/759,746

Applicant(s)

FERNANDEZ-SALAS ET AL.

Examiner

Chang-Yu Wang

Art Unit

1649

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 29 June 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 6/29/07. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: None.  
Claim(s) objected to: None.  
Claim(s) rejected: 1, 3-20, 22, 45-47, 56 and 57.  
Claim(s) withdrawn from consideration: None.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/CYW/

Continuation of 11. does NOT place the application in condition for allowance because:

The objection to the specification is maintained because the specification fails to point to specific portions of the referenced document where the subject matter being incorporated may be found. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition, the specification is objected to because the specification fails to indicate the relationship between the instant application and the cited applications. See MPEP 201.11 (II). "The third requirement of the statute is that the later-filed application must contain a specific reference to the prior application. This should appear as the first sentence(s) of the specification following the title preferably as a separate paragraph (37 CFR 1.78(a)) and/or in an application data sheet (37 CFR 1.76).".

Applicant's amendments and arguments are insufficient to overcome the rejection under 35USC 112-1<sup>st</sup> paragraph and the rejection under 103 (a).

Claims 3, 4, 46 and 47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement due to new matter for the reason made of record in Paper No.2006727. Applicant's arguments have been fully considered but they are not persuasive to obviate the rejection because the specification fails to specifically indicate what subject matter has been incorporated by the copending application 10/757077. In addition, 10/757077 fails to teach a method of identifying a compound that increases biological persistence of BoNT/A light chain by observing about 20-300% more BoNT/A light chain location to the plasma membrane (i.e. as it relates to claims 3, 46) and also fails to teach a method of identifying a compound that decreases biological persistence of BoNT/A light chain by observing about 10-90% reduction in plasma membrane location of the BoNT/A light chain (i.e. as it relates to claims 4 and 47). Thus, the limitations of observing 20-300% more or 10-90% reduction of BoNT/A on the plasma membrane recited in claims 3, 4, 46 and 47 are new matter.

Claims 1, 3-20, 22, 45-47, 56 and 57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6762280 (Schmidt et al. issued on Jul 13, 2004, effective filing date Sep 25, 2000) in view of Fernandez-Salas et al. (I. Society for Neuroscience Abstract Viewer and Itinerary Planner, 2003. Vol 2003, pp. Abstract No. 9.2.) or Fernandez-Salas et al. (II. Steward et al. Naunyn-Schmiedeberg's Archives of Pharmacology, June 2002. Vol. 365 No. Supplement 2, pp. R19), for the reasons made of record in Paper No.2006727. Applicant's arguments are not persuasive to obviate the rejection because Schmidt (US Patent No. 6762280) teaches a method for identifying a compound that either inhibits or enhances the proteolytic activity of botulinum neurotoxin serotype A (BoNT/A). Although Schmidt does not use a cell-based screening system for the screening steps, the references of Fernandez-Salas et al. I/II provide the steps of the screening method using the cell-based system by a fusion protein of the BoNT/A light chain to GFP protein and confocal microscopy to detect the colocalization of GFP-BoNT/A light chain with transfected SNAP25 in neurons. Thus, the claimed method is obvious over the teachings of Schmidt et al. (US Patent No. 6762280, Fernandez-Salas et al. (I) and (II)). In addition, the recitation of ranges of 20-300% increase or 10-90% decrease in claims 3, 4, 46, 47, 56 and 57 is routine optimization, which does not render the claimed invention patentable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re Sola*, 22 CCPA (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re Normann et al.*, 32 CCPA (Patents) 1248, 150 F.2d 627, 66 USPQ 308; *In re Irmischer*, 32 CCPA (Patents) 1259, 150 F.2d 705, 66 USPQ 314.

/CYW/  
7/9/07



ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER